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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF ILLINOIS
URBANA DIVISION

FRED KUMMEROW, on behalf of himself and the general public,

Plaintiff,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION; MARGARET HAMBURG, in her official capacity as Commissioner, United States Food and Drug Administration; CENTER FOR FOOD SAFETY AND APPLIED NUTRITION; MICHAEL M. LANDA, in his official capacity as Director, Center for Food Safety and Applied Nutrition; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; and KATHLEEN SEBELIUS, in her official capacity as Secretary, United States Department of Health and Human Services,

Defendants.

Case No: _____

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

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I. INTRODUCTION

1. The use of partially hydrogenated vegetable oils in the American food supply has contributed to a national epidemic of coronary heart disease, causing tens of thousands of excess deaths each year and billions of dollars of additional health care expenditures. The artificial trans fat in these oils is more harmful to cholesterol levels than dietary cholesterol or saturated fat, leading to blocked arteries and heart attacks. Dr. Julie Louise Gerberding, long-time head of the U.S. Centers for Disease Control and Prevention, summarized the scientific consensus in 2009, writing, "The scientific rationale for eliminating exposure to artificial trans fatty acids in foods is rock solid."

2. In addition to causing as many as 100,000 excess deaths per year from coronary heart disease (CHD), artificial trans fat from partially hydrogenated oils causes other deadly diseases, including type 2 diabetes, cancer, and Alzheimer's disease.

3. The statutory mission of Defendant the Food and Drug Administration (FDA) includes the duty to "protect the public health by ensuring that foods are safe, wholesome, sanitary, and properly labeled . . . ." 21 U.S.C. § 393(b)(2).

4. The Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 331, 342, 346, 348 and 393, requires the FDA to prohibit adulterated foods containing any poisonous or deleterious substances. Artificial trans fat is a poisonous and deleterious substance, and the FDA has acknowledged the danger:

> There is a positive linear trend between trans fatty acid intake and LDL cholesterol concentration, and therefore there is a positive linear relationship between trans fatty acid intake and the risk of CHD. . . . The [Institute of Medicine] sets tolerable upper intake levels (UL) for the highest level of daily nutrient intake that is likely to pose no risk of adverse health effects to . . . the general population. In their 2005 report, the IOM does not set a UL for trans

> fatty acid because any incremental increase in trans fatty acid intake increases the risk of CHD.

75 Fed. Reg. 76526, 76542 (Dec. 8, 2010).

5. The FDA's failure to ban the use of partially hydrogenated oils containing artificial trans fat in food for human consumption constitutes an agency action unlawfully withheld in violation of the Administrative Procedure Act (APA), 5 U.S.C. § 706(1), and the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 331, 342, 346, 348, and 393.

6. On August 4, 2009, Plaintiff Dr. Fred Kummerow submitted a citizen petition (the "Petition") to the FDA requesting that the agency ban the use of partially hydrogenated fats from food for human consumption. The Petition was assigned docket number FDA-2009-P-0382-0001/CP and accepted as filed on August 7, 2009. The FDA has never issued a final response to the Petition.

7. The FDA has unreasonably delayed ruling on the Petition in violation of the APA, 5 U.S.C. §§ 555(b) and 706, and the Food and Drug Act's implementing regulations, 21 C.F.R. § 10.30(e)1.

8. Plaintiff Dr. Kummerow seeks a judgment declaring that the FDA's failure to ban the use of partially hydrogenated oils and its delay in issuing a final response to the Petition violate the APA and the FDCA. Plaintiff also seeks an order compelling the FDA to respond to the Petition and to ban partially hydrogenated oils unless a complete administrative review finds new evidence for their safety, all by specific Court-ordered deadlines.

II. JURISDICTION AND VENUE

9. This Court has jurisdiction pursuant to 28 U.S.C. § 1331.

10. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(e), because Plaintiff resides in and has his principal place of employment in this judicial district and because no real property is involved.

11. This Court may award Plaintiff all necessary injunctive relief pursuant to the APA, 5 U.S.C. § 706, and may award declaratory relief pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

III. PARTIES

12. Plaintiff Fred Kummerow is Professor Emeritus at the University of Illinois's Department of Comparative Biosciences. During a career spanning over 60 years, Dr. Kummerow has conducted and published extensive research into the mechanisms by which cholesterol and artificial trans fat cause coronary heart disease. He first published on trans fat in 1957, and he was instrumental in convincing major industry actors to lower the artificial trans fat content of American oils and margarines in 1968, perhaps explaining a marked decrease in fatal coronary heart disease after 1968. Since then he has continued his detailed exploration of choelsterol, trans fat, and heart health, recently publishing findings that unnaturally oxidized cholesterol does greater damage to heart health than other forms of dietary cholesterol.

13. Defendants the FDA and Margaret Hamburg, in her official capacity as Commissioner of the FDA, are charged by the Food and Drug Act with protecting the public health by ensuring that food is safe. The FDCA requires the FDA to execute the statutory prohibitions on unsafe and adulterated food.

14. The FDCA implementing regulations and the APA also require Defendants the FDA and Hamburg to rule on citizen petitions within a reasonable period of time.

15. Defendants Center for Food Safety and Applied Nutrition (CFSAN) and Michael

M. Landa, in his official capacity as Director of the CFSAN, are charged by the Food and Drug Act and its implementing regulations with prohibiting unsafe and adulterated food.

16. Defendants United States Department of Health and Human Services (HHS) and Kathleen Sebelius, in her official capacity as Secretary of HHS, are charged with responsibility for the implementation and administration of relevant provisions of the Food and Drug Act.

17. For the purposes of this Complaint, Defendants the FDA, Margaret Hamburg, CFSAN, Michael M. Landa, HHS, and Kathleen Sebelius shall individually and collectively be referred to as the "FDA".

IV. STATUTORY AND REGULATORY FRAMEWORK

18. 21 U.S.C. § 331 prohibits adulterated food in interstate commerce. 21 U.S.C. § 342(a) specifies that a food shall be deemed adulterated if it "bears or contains any poisonous or deleterious substance which may render it injurious to health," or if it contains "any food additive that is unsafe."

19. 21 U.S.C. § 348 governs the safety of food additives and defines all additives as "unsafe" unless approved by appropriate regulation. Any person may file a petition for approval of a new food additive pursuant to 21 U.S.C. § 348(b), and § 348(i) provides that similar petition procedures may be used to amend or repeal such regulations.

20. If it is impossible or infeasible to completely eliminate a poisonous or deleterious substance from food, 21 U.S.C. § 346 specifically mandates that the Secretary of Health and Human Services "shall promulgate regulations limiting" the allowable quantities of the deleterious substance, "and any quantity exceeding the limits so fixed shall also be deemed to be unsafe."

21. According to 21 U.S.C. § 371(e)(1), "[A]ny interested person" may file a petition to initiate "the issuance, amendment, or repeal of any regulation under," *inter alia*, 21 U.S.C. § 346. Further, the Secretary shall "by order act upon such proposal" as "soon as practicable thereafter." *Id*. § 371(e)(1).

22. The Secretary of Health and Human Services "shall, through the Commissioner" of the FDA, "be responsible for executing" the FDCA. 21 U.S.C. § 393(d)(2). Accordingly, it is the FDA's authority and obligation to ensure food safety consistent with the foregoing statutes.

23. The Commissioner of the FDA has delegated responsibility for food standards and additive standards to the Director of the CFSAN. 21 C.F.R. § 5.61.

24. The FDA's regulations allow citizens to petition the FDA to "issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action." 21 C.F.R. § 10.25.

25. Consistent with this process, Plaintiff Fred Kummerow submitted the Petition seeking to ban partially hydrogenated oils in August 2009, pursuant to 21 C.F.R. § 10.30, following the form specified in § 10.30(b).

26. According to § 10.30(e)(2), "the [FDA] Commissioner shall furnish a response to each petitioner within 180 days of receipt of the petition." The response must approve, deny, or provide a tentative response to the petition indicating why the agency has not yet been able to reach a decision. 21 C.F.R. § 10.30(e)(2). In a tentative response, the Commissioner "may also indicate the likely ultimate agency response, and may specify when a final response may be furnished." *Id.* § 10.30(e)(2)(iii).

27. The Commissioner "may grant or deny such a petition, in whole or in part, and may grant such other relief or take other action as the petition warrants." 21 C.F.R. § 10.30(e)(3). The petitioner must be "notified in writing of the Commissioner's decision." *Id*.

V. FACTS

28. Artificial trans fat is manufactured in an industrial process called partial hydrogenation, in which hydrogen atoms are added to normal vegetable oil by heating the oil to temperatures above 400 degrees Fahrenheit in the presence of ion donor catalyst metals, such as rhodium, ruthenium, and nickel.[1] The resulting product is known as partially hydrogenated oil, an artificial fat which is the main source of artificial trans fat in the American diet.

29. Partially hydrogenated oil was invented in 1901 and patented in 1902 by German chemist Wilhelm Normann. Molecules in partially hydrogenated oils are chemically different from the natural fat molecules in other food products.[2]

30. Natural fat, except the trace amounts of natural trans fat from ruminant animals, comes in two varieties: (1) fats that lack carbon double bonds ("saturated fat") and (2) fats that have carbon double bonds with the hydrogen atoms on the same side on the carbon chain (natural unsaturated fat or "cis fat"). Trans fat, however, has double bonds on opposite sides of its carbon chain.

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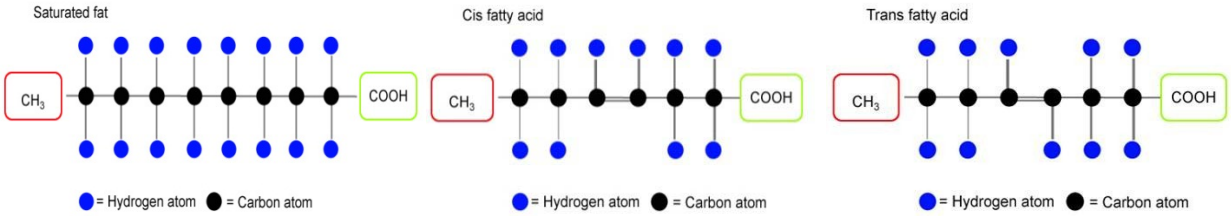
[1] *See* Alice H. Lichtenstein, *Trans Fatty Acids, Plasma Lipid Levels, and Risk of Developing Cardiovascular Disease*, 95 Circulation 2588, 2588-90 (1997).

[2] Alberto Ascherio et al., *Trans Fatty Acids & Coronary Heart Disease*, 340 New Eng. J. Med. 94, 94-98 (1999). *See also* Ctr. for Food Safety & Applied Nutrition, U.S. Food & Drug Admin., Questions & Answers About *Trans* Fat Nutrition Labeling (Update 2006) (2003), http://www.cfsan.fda.gov/%7Edms/qa*trans*2.html.



31. Partially hydrogenated oil was initially a "wonder product" attractive to the packaged food industry because it combines the low cost of unsaturated cis fat with the flexibility and long shelf life of saturated fat. Like cis fat, partially hydrogenated oil is manufactured from lower-cost legumes,[3] while saturated fat is derived from relatively expensive animal and tropical plant sources.[4] Given its versatility, this source of artificial trans fat was used in 40 percent of processed packaged foods as recently as 2002.[5]

32. Now, several decades of scientific research have shown artificial trans fat is extremely dangerous to consumers' health. Partially hydrogenated oil causes cardiovascular heart disease, diabetes, cancer, and Alzheimer's disease, and it accelerates cognitive decline in diabetics.

A. Plaintiff Petitioned the FDA to Ban Artificial Trans Fat from the American Diet

33. Plaintiff Fred Kummerow's own research in his faculty position at the University of Illinois has helped develop the scientific understanding of artificial trans fat's harmful effects. In 2009, he concluded in a peer-reviewed publication:

> Partially hydrogenated fats change plasma lipid levels in negative ways. They calcify cells and cause inflammation of the arteries, which are known risk

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[3] e.g., rapeseed, soy, and peanut oils

[4] e.g., butter, cream, tallow, coconut oil

[5] Mary Carmichael, *The Skinny on Bad Fat*, Newsweek, Dec. 1, 2003, at 66. *See also* Kim Severson, *Hidden Killer. It's Trans Fat. It's Dangerous. And It's In Food You Eat Every Day*, S.F. Chron., Jan. 30, 2002.

> factors in heart disease. They are not metabolized the same way as the trans vaccenic acid in ruminant fat and are not harmless. Trans fats inhibit . . . an enzyme which . . . is necessary to prevent blood clots in the arteries and veins. A blood clot in the coronary arteries can result in sudden death. . . . The only course to protect the health of consumers is to eliminate the production of partially hydrogenated trans fats.[6]

34. Dr. Kummerow's concern about the clear health danger posed to the general public and the failure of the FDA to take appropriate regulatory action led him to file his citizen petition in 2009, seeking to ban partially hydrogenated oils.

35. The Petition conforms in form and content to the requirements of 21 C.F.R. § 10.30. It contains a detailed explanation of the forms of fat created by the partial hydrogenation process, followed by a discussion of how trans fat causes coronary heart disease, including some history of how trans fat has been used and regulated over the last century.

36. Importantly, Dr. Kummerow explains in the Petition that the FDA fails to distinguish between artificial trans fat produced by hydrogenation and natural trans fat found in ruminant animal products in the form of vaccenic acid.[7] The FDA has previously said that a complete ban on trans fat would be impractical, because such a ban would disqualify many ordinary dairy products based on their vaccenic acid component,[8] but Dr. Kummerow shows that there is a clear scientific distinction between natural and artificial trans fat. His petition, of course, seeks to ban artificial trans fat, which occurs in the food supply only in partially hydrogenated oils. Vaccenic acid and artificial trans fat are chemically distinct and come from separate sources, meaning a ban on one need not affect the other.

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[6] Fred A. Kummerow, *The negative effects of hydrogenated trans fat and what to do about them*, Atherosclerosis 205:458-465 (2009).

[7] Petition at 3.

[8] 68 Fed. Reg. at 41445

37. The FDA sent Dr. Kummerow an acknowledgment of his petition on August 7, 2009. According to that communication ("Acknowledgment Letter"), the FDA accepted the Petition as filed on August 7, 2009, under the docket number FDA-2009-P-0382-0001/CP.

38. The Acknowledgment Letter noted that "the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition."

39. The FDA has never ruled on the Petition, and as of this filing, Dr. Kummerow has received no further notice about the status of his Petition.

B. Plaintiff Has Personally Suffered From the FDA's Failure to Ban Artificial Trans Fat.

40. Though Dr. Kummerow is an educated consumer who does his best to avoid consuming artificial trans fat, its ubiquity in both packaged food and restaurants makes it impossible for him to avoid completely.

41. Due to the FDA's failure to institute the ban he is seeking, Dr. Kummerow consumed artificial trans fat, damaging his cholesterol health and causing myriad cardiovascular problems that elevate his risk of coronary heart disease.

42. In February 2004, Dr. Kummerow himself learned from his doctor that his left coronary artery was 75% blocked. Dr. Kummerow underwent immediate coronary bypass surgery.

43. Artificial trans fat contributed to Dr. Kummerow's arterial blockage, leading to surgery. The ban on partially hydrogenated oils that Dr. Kummerow seeks would help prevent these sorts of dangerous medical situations.

44. The ongoing failure of the FDA to ban artificial trans fat puts consumers like Dr. Kummerow at daily risk from trans fat's damaging effects.

C. There Is a Well-Established Scientific Consensus that Trans Fat Is Extremely Harmful

45. There is "no safe level" of artificial trans fat intake.[9]

46. According to the established consensus of the scientific community, consumers should keep their consumption of trans fat "as low as possible."[10]

47. Dr. Julie Louise Gerberding, former director of the Center for Disease Control, writes in the Annals of Internal Medicine:

> The scientific rationale for eliminating exposure to artificial trans fatty acids in foods is rock solid. There is no evidence that they provide any health benefit, and they are certainly harmful. These compounds adversely affect both low- and high-density lipoprotein cholesterol levels and increase the risk for coronary heart disease, even at relatively low levels of dietary intake. Gram for gram, trans fats are far more potent than saturated fats in increasing the risk for heart disease, perhaps because they also have pro-inflammatory properties and other adverse effects on vascular endothelium. The strong evidence of harm motivated the Institute of Medicine to issue recommendations that the intake of trans fats be minimized and prompted the [FDA] to require the addition of information about trans fat content to food labels beginning in 2006. **Eliminating exposure to these dangerous fats could have a powerful population impact—potentially protecting 30,000 to 100,000 Americans from death related to heart disease each year.**[11] (emphasis added).

48. There is no longer any debate within the scientific community. Dariush Mozaffarian of Harvard Medical School writes in the New England Journal of Medicine:

> The evidence and the magnitude of adverse health effects of trans fatty acids are in fact far stronger on average than those of food contaminants or pesticide residues, which have in some cases received considerable attention. Furthermore, trans fats from partially hydrogenated oils have no intrinsic

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[9] Food & Nutrition Bd., Inst. of Med., *Dietary Reference Intakes For Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids* (2005).

[10] *Id.*

[11] Julie Louise Gerberding, MD, MPH, *Safer Fats for Healthier Hearts: The Case for Eliminating Dietary Artificial Trans Fat Intake*, Ann. Intern. Med., 151:137-138 (2009).

> health value above their caloric value. Thus from a nutritional standpoint, the consumption of trans fatty acids results in considerable potential harm but no apparent benefit. . . . Thus, complete or near-complete avoidance of industrially produced trans fat—a consumption of less than 0.5 percent of the total energy intake—may be necessary to avoid adverse effects and would be prudent to minimize health risks.[12]

49. Given its nature as an artificial chemical not naturally found in any food and the considerable harm that it causes to human health, Dr. Walter Willet of the Harvard School of Public Health also finds the most direct analogue of trans fat to be not any natural fat but contaminants such as pesticides. He states that banning trans fat "is a food safety issue . . . this is actually contamination."[13]

D. Artificial Trans Fat Is so Dangerous that It Has Been Banned by an Increasing Number of American States and Governments Abroad

50. In 2008, California became the first state to ban all restaurant food with artificial trans fat in quantities greater than half a gram per serving, a law affecting approximately 88,000 eating establishments. Artificial trans fats now may not be served in California's schools or restaurants in an amount greater than half a gram per serving.[14]

51. New York City banned trans fat in quantities greater than half a gram per serving in its 20,000 food establishments in 2006. Similar laws exist in Philadelphia; Baltimore; Stamford, Connecticut; and Montgomery County, Maryland.

52. A 2004 Danish law limited all fats and oils for human consumption to 2%

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[12] Dariush Mozaffarian, *et al.*, *Trans Fatty Acids and Cardiovascular Disease*, 354 N. Engl. J. Med. 1601, 1608-1609 (2006).

[13] Rebecca Coombes, *Trans fats: chasing a global ban*, 343 British Med. J. d5567 (2011).

[14] Cal. Educ. Code § 49431.7; Cal. Health & Saf. Code § 114377.

artificial trans fat, effectively a complete ban. Switzerland enacted similar restrictions in 2008.[15]

53. Austria, Brazil, Argentina, Chile and South Africa have also taken steps to reduce or eliminate trans fats from food.[16]

54. In 2006, a trans fat task force co-chaired by Health Canada and the Heart and Stroke Foundation of Canada recommended capping trans fat content at 2 percent of calories for tub margarines and spreads and 5 percent for all other foods. On September 30, 2009, British Columbia became the first province to impose these rules on all restaurants, schools, hospitals, and special events.[17]

E. Artificial Trans Fat Causes Cardiovascular Disease

55. The American Heart Association warns, "trans fats raise your bad (LDL) cholesterol levels and lower your good (HDL) cholesterol levels. Eating trans fats increases your risk of developing heart disease."[18]

56. By raising LDL levels and lowering HDL levels, trans fat causes a wide variety of dangerous heart conditions, including low flow-mediated vasodilation, coronary artery disease, and primary cardiac arrest.

57. Trans fat raises the risk of CHD more than any other known nutritive product.[19]

58. Removing trans fat equal to 2% of total calories from the American diet "would

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[15] Andrew Collier, *Deadly Fats: Why Are We still Eating Them?*, The Independent (UK), June 10, 2008.

[16] Coombes, 343 British Med. J. d5567.

[17] *Province Restricts Trans Fat in B.C.*, British Columbia Ministry of Healthy Living and Sport Press Release (2009), http://www2.news.gov.bc.ca/news_releases_2005-2009/2009HLS0013-000315.htm.

[18] Am. Heart Ass'n., *Trans Fat Overview*, http://www.heart.org/HEARTORG/GettingHealthy/FatsAndOils/Fats101/Trans-Fats_UCM_301120_Article.jsp

[19] Mozaffarian, 354 New Eng. J. Med. at 1603.

prevent approximately 30,000 premature coronary deaths per year, and epidemiologic evidence suggests this number is closer to 100,000 premature deaths annually."[20]

59. "10 to 19 percent of CHD events in the United States could be averted by reducing the intake of trans fat."[21]

60. In a joint Dietary Guidelines Advisory Committee Report, the Department of Health and Human Services and the U.S. Department of Agriculture recognized "[t]he relationship between trans fatty acid intake and LDL cholesterol is direct and progressive, increasing the risk of cardiovascular disease."[22]

61. After a review of literature on the connection between the consumption of artificial trans fat and coronary heart disease, the FDA concluded:

> [B]ased on the consistent results across a number of the most persuasive types of study designs (i.e., intervention trials and prospective cohort studies) that were conducted using a range of test conditions and across different geographical regions and populations . . . the available evidence for an adverse relationship between trans fat intake and CHD risk is strong.[23]

62. The FDA further found "[t]o date, there have been no reports issued by authoritative sources that provide a level of trans fat in the diet . . . below which there is no risk of [CHD]."[24]

63. One study by Harvard School of Public Health researchers investigating the

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[20] Alberto Ascherio et al., *Trans Fatty Acids & Coronary Heart Disease*, Background and Scientific Review. Published online concurrently with Alberto Ascherio *et al.*, *Trans Fatty Acids & Coronary Heart Disease*, 340 New Eng. J. Med. 94, 94-98 (1999).

[21] Mozaffarian, 354 New Eng. J. Med. at 1611.

[22] Dep't of Health & Human Serv. & U.S. Dep't of Agric., 2005 Dietary Guidelines Advisory Committee Report, Section 10 (2005).

[23] Ctr. for Food Safety & Applied Nutrition, U.S. Food & Drug Admin., Questions & Answers About *Trans* Fat Nutrition Labeling.

[24] 75 Fed. Reg. 76526, 76542 (Dec. 8, 2010).

impact of trans fatty acids on heart health provides evidence that:

> [E]ven the lower estimates from the effects [of trans fat] on blood lipids would suggest that more than 30,000 deaths per year may be due to the consumption of partially hydrogenated vegetable fat. Furthermore, the number of attributable cases of nonfatal coronary heart disease will be even larger.[25]

64. By taking blood samples from 179 survivors of cardiac arrest and 285 randomly-selected control patients and comparing the top fifth with the bottom fifth of participants by trans fat intake, a study published in the American Heart Association's Circulation found that the largest consumers of trans fat have three times the risk of suffering primary cardiac arrest, even after controlling for a variety of medical and lifestyle risk factors.[26]

65. Australian researchers observed that heart attack patients possess elevated amounts of trans fat in their adipose tissue, strongly linking heart disease with long-term consumption of trans fat.[27]

F. Artificial Trans Fat Causes Type 2 Diabetes

66. Artificial trans fat causes type 2 diabetes.[28]

67. In particular, trans fat disrupts the body's glucose and insulin regulation system by incorporating itself into cell membranes, causing the insulin receptors on cell walls to malfunction, in turn elevating blood glucose levels and stimulating further release of insulin.

68. Researchers at Northwestern University's medical school found mice show

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[25] W.C. Willett et al., *Trans Fatty Acids: Are the Effects only Marginal?*, 84 Am. J. Pub. Health 722, 723 (1994).

[26] Rozenn N. Lemaitre et al., *Cell Membrane Trans-Fatty Acids and the Risk of Primary Cardiac Arrest*, 105 Circulation 697, 697-701 (2002).

[27] Peter M. Clifton et al., *Trans Fatty Acids In Adipose Tissue And The Food Supply Are Associated With Myocardial Infarction*. 134 J. Nutrition 874, 874-79 (2004).

[28] Am. Heart Ass'n., *Trans Fat Overview*.

multiple markers of type 2 diabetes after eating a high trans fat diet for only four weeks.[29]

69. By the eighth week of the study, mice fed the diet high in trans fat showed a 500 percent increase compared to the control group in hepatic interleukin-1β gene expression, one such marker of diabetes, indicating the extreme stress artificial trans fat places on the body.[30]

70. A 14-year study of 84,204 women found that for every increase in artificial trans fat consumption equal to 2 percent of total energy intake, the relative risk of type 2 diabetes was increased by 39 percent.[31]

G. Artificial Trans Fat Causes Breast, Prostate, and Colorectal Cancer

71. Trans fat is a carcinogen and causes breast, prostate, and colorectal cancer.

72. A 13-year study of 19,934 French women showed 75 percent more women contracted breast cancer in the highest quintile of trans fat consumption than those in the lowest.[32]

73. In a 25-year study of 14,916 U.S. physicians, the doctors in the highest quintile of trans fat intake had more than double the risk of developing prostate cancer than the doctors in the lowest quintile.[33]

74. A study of 1,012 American males observing trans fat intake and the risk of prostate cancer found, "[c]ompared with the lowest quartile of total trans-fatty acid

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[29] Sean W. P. Koppe et al., *Trans fat feeding results in higher serum alanine aminotransferase and increased insulin resistance compared with a standard murine high-fat diet*, 297 Am. J. Physiol. Gastrointest Liver Physiol. G378-84 (2009).

[30] *Id.*

[31] Jorge Salmeron et al., *Dietary Fat Intake and Risk of Type 2 Diabetes in Women*, 73 Am. J. Clinical Nutrition 1019, 1023 (2001).

[32] Véronique Chajès et al., *Association between Serum Trans-Monounsaturated Fatty Acids and Breast Cancer Risk in the E3N-EPIC Study.* 167 Am. J. Epidemiology 1312, 1316 (2008).

[33] Jorge Chavarro et al., *A Prospective Study of Blood Trans Fatty Acid Levels and Risk of Prostate Cancer.*, 47 Proc. Am. Assoc. Cancer Research 95, 99 (2006).

consumption, the higher quartiles gave odds ratios (ORs) equal to 1.58," meaning those in the highest quartile are 58 percent more likely to contract prostate cancer than those in the lowest.[34]

75. A 600-person study found an 86 percent greater risk of colorectal cancer in the highest trans fat consumption quartile.[35]

76. A 2,910-person study found "trans-monounsaturated fatty acids . . . were dose-dependently associated with colorectal cancer risk," which showed "the importance of type of fat in the etiology and prevention of colorectal cancer."[36]

H. Artificial Trans Fat Causes Alzheimer's Disease and Cognitive Decline

77. Trans fat causes Alzheimer's Disease and cognitive decline.

78. In a study examining 815 Chicago area seniors, researchers found "increased risk of incident Alzheimer disease among persons with high intakes of . . . trans-unsaturated fats."[37]

79. The study "observed a strong increased risk of Alzheimer's disease with consumption of trans-unsaturated fat."[38]

80. In another study of 1,486 women with type 2 diabetes, researchers found "[h]igher intakes of . . . trans fat since midlife . . . were [] highly associated with worse cognitive decline . . . ."[39]

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[34] Xin Liu et al., *Trans-Fatty Acid Intake and Increased Risk of Advanced Prostate Cancer: Modification by RNASEL R462Q Variant*, 28 Carcinogenesis 1232, 1232 (2007).

[35] L.C. Vinikoor et al., *Consumption of Trans-Fatty Acid and its Association with Colorectal Adenomas*, 168 Am. J. of Epidemiology 289, 294 (2008).

[36] Evropi Theodoratou et al., *Dietary Fatty Acids and Colorectal Cancer: A Case-Control Study*, 166 Am. J. Epidemiology 181 (2007).

[37] Martha Clare Morris et al., *Dietary Fats and the Risk of Incident Alzheimer Disease*, 60 Arch. Neurol. 194, 198-99 (2003).

[38] *Id.*

[39] Elizabeth E. Devore et al., *Dietary Fat Intake and Cognitive Decline in Women with Type 2 Diabetes*, 32 Diabetes Care 635 (2009).

81. The study cautioned "[d]ietary fat intake can alter glucose and lipid metabolism and is related to cardiovascular disease risk in individuals with type 2 diabetes. Because insulin, cholesterol, and vascular disease all appear to play important roles in brain aging and cognitive impairments, dietary fat modification may be a particularly effective strategy for preventing cognitive decline, especially in individuals with diabetes."[40] (citations omitted).

I. Artificial Trans Fat Causes Damage to Vital Organs

82. Artificial trans fat damages vital organs, including the heart, by causing chronic systemic inflammation, in which the immune system becomes persistently overactive, damages cells, and causes organ dysfunction.[41]

J. The FDA Has Recognized the Widespread Damage Caused by Artificial Trans Fat

83. After an extensive review of the best available scientific evidence, the FDA itself has concluded, without reservation, that the consumption of artificial trans fat causes heart disease. For example, in the final rule issued in 2003 that required trans fat content be listed on product packaging, the FDA wrote:

> FDA continues to find that a large body of the most persuasive types of evidence (i.e., intervention trials and prospective cohort observational studies) consistently show that trans fat intakes adversely affect CHD risk under both controlled trial conditions and in free-living populations following their usual dietary patterns. This consistency was seen across studies done: (1) In the United States and several European countries, (2) using a variety of test and control products and study designs, (3) using a range of intake levels

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[40] *Id.*

[41] *See* Lopez-Garcia *et al*., *Consumption of Trans Fat is Related to Plasma Markers of Inflammation and Endothelial Dysfunction,* 135 J. Nutr. 562 (2005); *see also* Baer *et al.*, *Dietary fatty acids affect plasma markers of inflammation in healthy men fed controlled diets; a randomized crossover study,* 79 Am. J. Clin. Nutr. 969 (2004); Mozaffarian & Clarke, *Quantitative effects on cardiovascular risk factors and coronary heart disease risk of replacing partially hydrogenated vegetable oils with other fats and oils,* 63 Euro. J. Clin. Nutr. S22-S33 (2009); Mozaffarian *et al.*, *Trans Fatty acids and systemic inflammation in heart failure,* 80 Am. J. Clin. Nutr. 1521-25 (2004).

> for trans fatty acids (less than (<) 1 percent to 7 percent of calories), (4) by different investigators and research groups, (5) with different populations and selection/exclusion criteria, and (6) within different total dietary contexts. This relationship was also consistently found in comparisons of high vs. low consumers of trans fats in free-living U.S. populations consuming their normal diets. Thus, whether controlled intervention trials or among free-living U.S. populations consuming their usual diets, the adverse effects of trans fat intakes on CHD risk were consistently observed.[42]

By 2006, the ironclad evidence of danger had only grown stronger, and the FDA reiterated its conclusion that trans fat is unsafe:

> There is a positive linear trend between trans fatty acid intake and LDL cholesterol concentration, and therefore there is a positive relationship between trans fatty acid intake and the risk of CHD. . . . The [Institute of Medicine] sets tolerable upper intake levels (UL) for the highest level of daily nutrient intake that is likely to pose no risk of adverse health effects to . . . the general population. In their 2005 report, the IOM does not set a UL for trans fatty acid because any incremental increase in trans fatty acid intake increases the risk of CHD.[43]

The same passage also notes that "*trans* fatty acids are not essential and provide no known benefit to human health."

84. The FDA estimated that its 2003 rule requiring trans fat labeling on packaged foods "would annually prevent 600 cases of CHD and 240 deaths" from CHD. "Preventing 240 deaths would annually save about 1,920 discounted life years," and the nonfatal cases add additional costs of about $282,000 per case, measured in quality of life and medical expenses after a non-fatal cardiac event.[44]

85. A complete ban of artificial trans fats would prevent many more deaths and heart attacks than simple labeling regulations. Epidemiologists estimate that the complete removal of

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[42] 68 Fed. Reg. 41434, 41444 (July 11, 2003).

[43] 75 Fed. Reg. 76526, 76542 (Dec. 8, 2010)

[44] 68 Fed. Reg. 41488.

artificial trans fat from the American diet would prevent 30,000 deaths per year from coronary heart disease, and evidence suggests that figure could be closer to 100,000 lives saved annually.[45] The corresponding prevention of non-fatal events, extrapolating from the FDA's 2003 estimates, would save over $2.5 billion dollars annually in medical treatment costs.

K. Previous FDA Decisions Failing to Ban Artificial Trans Fat Were Based on a Failure to Distinguish Partially Hydrogenated Oils and Natural Sources of Trans Fat.

86. In deciding to require trans fat labeling on packaged foods, the FDA relied on findings by the Institute of Medecine and National Academy of Science (IOM/NAS), that "a positive linear trend between trans fatty acid intake" and an "increased risk of CHD" suggested "an upper limit of zero," meaning no amount of trans fat consumption is acceptable, no matter how small.

87. These findings would mandate a complete ban on trans fat, but the IOM/NAS

> further stated that, because trans fatty acids are unavoidable in ordinary diets, a complete avoidance of these fats is not possible without extraordinary changes in patterns of dietary intake. Such extraordinary adjustments may introduce other undesirable effects (e.g., elimination of foods such as dairy products and meats that contain trans fatty acids may result in inadequate intakes of protein and certain macronutrients). For these reasons, the IOM/NAS recommended that trans fatty acid consumption be as low as possible while consuming a nutritionally adequate diet.[46]

88. Since the FDA's analysis in 2003, a growing body of scientific evidence has shown that there is a clear difference between natural trans fat, which appears in dairy products and some meats from ruminant animals in the form of vaccenic acid, and artificial trans fat, which appears in partially hydrogenated oils.

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[45] Ascherio, Background and Scientific Review (*see supra* n. 23), Gerberding, 151 Ann. Intern. Med. at 137; Mozaffarian, 354 New Eng. J. Med. at 1610, Fig. 5.

[46] 68 Fed. Reg. 41445.

89. A 2013 review published by the World Health Organization summarized:

> Human consumption of naturally occurring TFAs from ruminants is generally low and there is evidence to suggest that it does not adversely affect health. In contrast, consumption of industrially produced partially hydrogenated vegetable oils has been associated with an increased risk of cardiovascular disease, infertility, endometriosis, gallstones, Alzheimer's disease, diabetes and some cancers.[47]

90. Dr. Kummerow explained this distinction in his Petition, writing, "Epidemiological studies of intake of ruminant trans fat and risk of coronary heart disease (CHD) indicated that the intake of ruminant trans fatty acid was innocuous or even protective against CHD."

91. It would be simple as a legal matter for the FDA to ban partially hydrogenated oils and the artificial trans fats they contain, thus leaving natural sources of trans fat unregulated and avoiding any of the undesirable dietary effects that concerned the IOM/NAS in 2003. The FDA therefore has no remaining pretext to allow harmful artificial trans fats from partially hydrogenated oils in American food products.

L. Implementing a Ban on Artificial Trans Fat Can Be Quick and Low-Cost.

92. Experience from local- and state-level trans fat restrictions, as well as bans in nations such as Denmark and Switzerland, demonstrate that a complete ban on partially hydrogenated vegetable oils poses no undue burden to food producers and would create no unintended negative health consequences for consumers.

93. Denmark's trans fat ban, effective January 1, 2004, specifically mandated that industrially-produced fats intended for use in food should be limited to 2% trans fat by composition (partially hydrogenated oils often range from 25-35% trans fat), while naturally

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[47] Shauna Downs, *The effectiveness of policies for reducing dietary trans fat: a systematic review of the evidence*, Bulletin of the World Health Organization 2013;91:262-269.

occurring trans fat remains unaffected by the law. A review just two years later found broad compliance with the healthier standards and concluded that "producers have . . . developed new methods of production without increasing prices or reducing the availability of food."[48]

94. Another review concluded that "[b]oth government and industry representatives agreed" Denmark's ban on partially hydrogenated oils "did not appreciably affect the quality, cost, or availability of food."[49]

95. Partly in anticipation of local bans on partially hydrogenated oils in restaurants, led by New York City's 2006 legislation banning artificial trans fat in restaurant foods,

> Several large food outlet chains have . . . voluntarily removed trans-fat from their offerings nationally since 2006. These companies did not suffer any earnings loss . . . . For food companies, many alternatives to oils containing artificial trans-fat were available at comparable prices and tastes. Industry showed that the technology is readily available for food businesses to replace trans-fat with healthier options with minimal negative impact for cost or revenue.[50]

96. Industry has already demonstrated its ability to rapidly reformulate food products to minimize partially hydrogenated oils. A complete ban therefore presents little economic friction.

M. The FDA Has Taken Prompt Action on Petitions Proposing Far Less Important Changes.

97. The FDA has failed its regulatory obligation by ignoring Dr. Kummerow's petition indefinitely, but its inaction also demonstrates its unequal and inconsistent treatment of

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[48] Torben Leth et al., *The effect of the regulation on* trans *fatty acid content in Danish food*. 7 Atherosclerosis 53, 56 (2006).

[49] Mozaffarian, 354 New Eng. J. Med. at 1610; *see also* Karsten Nielsen, *Is the quality and cost of food affected if industrially produced trans fatty acids are removed?* Atherosclerosis 7 (2006) 61-62; Stender, Steen. *High Levels of Industrially Produced* Trans *Fat in Popular Fast Food*, 354 New Eng. J. Med. 1650, 1652 (2006).

[50] Andy S.L. Tan, *A case study of the New York City trans-fat story for international application*, J. Public Policy, Vol. 30, I, 3-16, 8.

citizen petitions.

98. The FDA's records show that numerous petitions were granted a final ruling in far less time than the four years Dr. Kummerow has already waited.

99. After a winery filed a petition seeking approval for a new color additive, the FDA took just over a year to issue a final rule approving the additive.[51]

100. In 2012, the FDA took just five months to respond to a petition by the American Chemical Council (FDA Docket No. FAP 1B4783) to remove polycarbonate resins from baby bottles.[52]

101. After the Quaker Oats company filed a petition in 2005 seeking permission to use a certain health claim on food labeling, the FDA issued a proposed rule in under two years.[53]

102. In 2003, the FDA published an advanced notice of proposed rulemaking as requested by a petition filed by the yogurt industry in 2000, requesting a change in the standards of identity for yogurt.[54]

103. In October 1993, the FDA responded to a citizen petition filed under 21 C.F.R. §10.30 by Hershey Foods on December 15, 1992 (FDA Docket No. 93P-0310). The FDA approved a test run of white chocolate products as a precursor to a new standard of identity for white chocolate, as Hershey Foods requested.

104. It has now been almost four years since the FDA acknowledged receipt of Dr. Kummerow's Petition. Dr. Kummerow has heard nothing further from the FDA regarding the

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[51] 78 Fed. Reg. 35115, 35115 (June 12, 2013).

[52] 77 Fed. Reg. 41899, 41899 (July 17, 2012).

[53] 73 Fed. Reg. 23947, 23948 (May 1, 2008).

[54] 74 Fed. Reg. 2443, 2444-2445 (January 15, 2009).

status of his petition.

VI. FIRST CLAIM FOR RELIEF
Agency Action Unlawfully Withheld

105. Plaintiff incorporates by reference all preceding paragraphs.

106. The FDCA requires the FDA to execute the provisions of the FDCA, including its prohibition of adulterated food containing poisonous or deleterious substances. 21 U.S.C. §§ 342, 348, and 393(d)(2). Further, in the event that an unsafe substance is impossible to eliminate completely, the FDCA requires the FDA to set a tolerable upper limit on the amount of the substance allowed in food. 21 U.S.C. § 346.

107. The scientific consensus on the deleterious health effects of partially hydrogenated oils is clear, and the FDA itself has recognized the causal link between artificial trans fat and CHD. The FDA has failed to comply with its statutory duty by failing to ban this harmful substance.

108. FDA's failure to ban partially hydrogenated oils from food constitutes an agency action unlawfully withheld or unreasonably delayed in violation of the APA, 5 U.S.C. § 706(1), and the FDCA, 21 U.S.C. §§ 342, 346, and 348.

VII. SECOND CLAIM FOR RELIEF
Arbitrary, Capricious, Abuse of Discretion, Otherwise Not in Accordance with the Law

109. Plaintiff incorporates by reference all preceding paragraphs.

110. The FDA's failure to comply with its statutory duty further constitutes an agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law," in violation of the APA, 5 U.S.C. § 706(2)(a).

VIII. THIRD CLAIM FOR RELIEF
Agency Action Unreasonably Delayed

111. Plaintiff incorporates by reference all preceding paragraphs.

112. The FDA has delayed unreasonably in issuing a response to the Petition submitted by Plaintiff in 2009.

113. The FDA's failure to issue a final response constitutes an agency action unreasonably delayed in violation of the APA, 5 U.S.C. §§ 555(b) and 706(1), and the FDCA's implementing regulations, 21 C.F.R. § 10.30(e)(1).

IX. PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of himself and the general public, prays for judgment against Defendants as follows:

A. Declaring that the FDA's failure to ban partially hydrogenated oils from food is unlawful, pursuant to the APA, 5 U.S.C. §§ 706, and the FDCA, 21 U.S.C. §§ 342, 346, and 348;

B. Declaring that the FDA's delay in issuing a final response to the Petition is unreasonable and unlawful, pursuant to the APA, 5 U.S.C. §§ 555(b) and 706(1), and the FDCA's implementing regulations, 21 C.F.R. § 10.30(e)(1);

C. Compelling the FDA to recognize partially hydrogenated oils as unsafe and ban their use in food by a Court-ordered deadline;

D. Compelling the FDA to issue a final response to the Petition, by a Court-ordered deadline;

E. Awarding Plaintiff his reasonable costs and attorneys' fees; and

F. Granting such other and further relief as the Court deems just and proper.

DATED: August 9, 2013

Respectfully Submitted,

/s/ Gregory S. Weston

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